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In The

Supreme Court of the United States

October Term, 1995

MENTOR CORPORATION,

Petitioner,

vs.

SAM FELDT,

Respondent.

Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Fifth Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Is a product liability claim arising under state law, alleging that a Class III medical device was defectively designed by its manufacturer, preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a) (1976), where the Food and Drug Administration approved the release of the device to the market under its "510(k)" regulatory procedure?

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PETITION FOR A WRIT OF CERTIORARI

Mentor Corporation[1] petitions this Court to issue a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this cause, in which the court of appeals held that a state law "design defect" product liability claim is not preempted under the Medical Device Amendments to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a), because the device was approved for release to the market under the Food and Drug Administration's "510(k)" procedure. The courts of appeals for the Third and Fourth Circuits reached the opposite conclusion in *English v. Mentor Corporation*, 67 F.3d 477 (CA 3, 1995), and *Duvall v. Bristol-Myers-Squibb Co.*, 65 F.3d 392 (CA 4, 1995), respectively. This conflict among the circuits is also drawn to the attention of this Court by the pending petition in *Medtronics Inc. v. Lohr*, No. 95-754.

OPINIONS BELOW

The opinion of the court of appeals (App. 1-17) is published at 61 F.3d 431 (CA5, 1995). The Memorandum and Order of the United States District Court for the Southern District of Texas, granting petitioner Mentor's motion for summary judgment (App. 20-29) is not published.

[1] Pursuant to Rule 29.6, we advise the Court that Mentor Corporation has no parent company, and has no subsidiaries that are not wholly-owned.

JURISDICTION

The court of appeals, whose jurisdiction was invoked under 28 U.S.C. § 1291, entered its judgment on August 21, 1995. Mentor filed a timely petition for rehearing, which was denied on September 26, 1995. App. 18-19. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTES AND REGULATIONS INVOLVED

This case involves the state law preemption provision of the Medical Device Amendments ("MDA") to the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a) (1976), which provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

Also involved are the "510(k) procedure" regulations of the Food and Drug Administration, 21 C.F.R. §§ 807.81-807.100, a procedure since codified by the Safe Medical Devices Act, 21 U.S.C. §§ 360(k), 360c(f) and (i) (1990). The relevant provisions of these additional statutes and regulations are printed at App. 30-40.

STATEMENT OF THE CASE

The question presented is essentially the same as that now before the Court in the petition in *Medtronics, Inc. v. Lohr*, No. 95-754. Therefore, we shall be as brief as possible.

A. Proceedings Below

This is a product liability action arising under state law, commenced in a Texas court, and removed to the district court under the diversity grant, 28 U.S.C. §§ 1332, 1441. In 1988, respondent Feldt underwent the surgical implantation of a penile prosthesis manufactured by petitioner Mentor. Evidently, the device worked fine until 1991, when it allegedly failed and was replaced. Feldt sued Mentor in 1993, seeking the usual damages for episodes of this nature. App. 1-2, 20-21.

Under various legal theories, modern product liability litigation typically assails defects in the product's design and manufacture, and the warnings given or omitted by its producer. Respondent's claims were of these types, but because the prosthesis was an FDA-approved Class III medical device, 21 C.F.R. § 876.3550(b), preemption under 21 U.S.C. § 360k(a) occupied center stage below. All Class III medical devices are, of course, subject to the FDA's labeling and good manufacturing practices ("GMP") regulations, 21 C.F.R. §§ 801.1, *et seq.*; §§ 820.1, *et seq.*[2] In addition, no Class III device introduced after the

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[2] In addition, further specific GMP regulations apply only to critical and prescription devices, such as the penile prosthesis involved in this case. *See* 21 C.F.R. § 820.5(f).

1976 effective date of the MDA may be marketed without prior approval of the FDA. Such agency approval may be obtained either under (1) FDA Investigational Device Exemption ("IDE") procedures, (2) the "510(k)" procedures applicable to devices determined to be "substantially equivalent" to those on sale before the adoption of the MDA, or (3) the FDA's premarket approval ("PMA") procedures. *See post*, pp. 6-8.

The prosthesis involved in this case was of a design first approved for human use under an IDE granted in 1986, after which petitioner conducted the clinical trials necessary to test the safety and effectiveness of the device. In 1987, petitioner then submitted a 510(k) application, which included substantial data on the safety and efficacy of the device, much of it gathered during the clinical trials conducted during the IDE phase. After reviewing all the information submitted, the FDA granted the 510(k) application, releasing the device for general use in the medical community. No alternative PMA was ever sought or granted, because none was ever required. On a full record of these facts, the district court held that all of respondent's claims were preempted, and granted petitioner's motion for summary judgment. App. 23-28.

The court of appeals affirmed in part and reversed in part. It agreed with the district court that respondent's "failure to warn" claims were preempted by reason of the agency's regulation of the labeling of medical devices, 21 C.F.R. §§ 801.1, *et seq.* App. 8-11. This is a view shared by other courts of appeals, *e.g.*, *Lohr v. Medtronics, Inc.*, 56 F.3d 1335, 1350-52 (CA 11, 1995), *pet'n for cert. pend'g*, No.

95-754; *Duvall v. Bristol-Myers-Squibb Co., supra,* 65 F.3d at 399-400.[3]

On the "defective design" claim, however, the court of appeals reversed the district court, and held that respondent's defective design claim was not preempted. Respondent's essential argument was that the FDA's 510(k) review and approval process is not as stringent as the agency's PMA process, to which the district court replied: "The MDA does not require a threshold level of [regulatory] stringency that must be met before preemption attaches." App. 27.

The court of appeals, however, took the opposite view. It held that 21 U.S.C. § 360k(a) does not preempt design-defect claims involving 510(k)-approved devices because (1) although the 510(k) process requires a demonstration that the device is "as safe and effective as a predicate device," (2) still there are no "general Class III regulations specifically concerning the safety or adequacy of the [penile implant's] design" and, therefore, under the 510(k) process, the FDA theoretically could

> approve an unreasonably dangerous device so long as the device . . . is as safe and effective as the predicate device. 21 U.S.C. § 360c(i). To say

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[3] There is also much agreement that the FDA's GMP (good manufacturing practices) regulations serve to preempt claims of "defective manufacture." *See id.* and *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1422 & n.5 (CA 5), *cert. denied,* 114 S.Ct. 86 (1993). The court of appeals, however, found it unnecessary to revisit its holding in *Stamps* because, at oral argument, respondent's counsel "maintained that he is not pursuing a warranty claim based upon defective manufacture, but only on defective design." App. 13.

> that a new device is as safe as its predicate thus indicates nothing, absolutely, about how safe either product is; a new device may be as safe as a predicate device that itself is unreasonably dangerous.

App. 13-16 & n.12. On this basis, the court of appeals distinguished its holding in *Stamps v. Collagen Corp., supra,* 984 F.2d at 1422, that device approval under the more stringent PMA process does trigger preemption of design defect claims because "PMA devices are deemed 'safe and effective.' " App. 13-14 & n.9.

This decision accords with that of the Eleventh Circuit in *Lohr,* but is in direct conflict with the decisions of the Third and Fourth Circuits in *English* and *Duvall,* respectively. Agency approval under the 510(k) process thus triggers preemption in design defect cases brought in the Third and the Fourth Circuits, but not in those brought in the Fifth and Eleventh. The conflict between the decision below and that of the Third Circuit in *English* is particularly ironic, as both cases involve the same device, the same manufacturer, and the same 510(k) review and marketing approval of the FDA.

B. Source of the Circuit Conflict: 510(k) and Premarketing Approval Procedures Under the Medical Device Amendments

This circuit conflict arises from differences in the way that Congress treated medical device approval procedures in the MDA, albeit differences that Congress chose not to recognize in the preemption provision of the statute. The opinion of the Third Circuit in *English v.*

Mentor Corporation, supra, 67 F.3d at 479, n.1, provides a useful summary of medical device approval procedures:

> "In adopting the MDA, Congress drew a distinction between devices that were on the market before its passage (and devices 'substantially equivalent' to these devices) and devices marketed after its passage in 1976. Congress realized that it was impracticable to require that devices that were already on the market be withdrawn until they obtained premarket approval from the FDA. See *21 U.S.C. § 360e.* Instead, Congress directed the FDA to promulgate regulations to allow manufacturers of these devices to move gradually into compliance with the MDA. Id. This authority also extended to new devices 'substantially equivalent' to devices on the market as of 1976. Id.
>
> "The FDA relied on this distinction as authorization for its 510(k) process. Thus, the FDA has issued regulations, such as 21 C.F.R. § 876, classifying certain preexisting devices (including inflatable penile implants) as Class III devices, but exempting them from immediate premarket approval (by postponing the date the regulations become effective). The FDA also allowed substantial equivalents of these devices to be marketed before obtaining final premarket approval – by completing the 510(k) process. Id. at §§ 807.81-807.100. These devices, however, are required to obtain premarket approval in the future. See 21 C.F.R. § 870.1-870.3. New devices (i.e. devices not in existence before 1976 or substantially equivalent to such a device) must receive premarket approval before they may be marketed. *21 U.S.C. § 360e(a);* 21 C.F.R. § 870.3.

> "With the passage of the Safe Medical Devices Act ('SMDA') in 1990, Pub. L. No. 101-629, Congress explicitly codified these 510(k) procedures. See H.Rep. No. 101-808, 101st Cong., 2d Sess., 1990 U.S.C.C.A.N. 6305, 6319 ('Section 4(b) [of the SMDA] codifies the FDA's current practice regarding the use of the 510(k) procedure for entering the market.'). The current approach is found at *21 U.S.C. § 360c*(f)(3), which explicitly allows a manufacturer of a Class III device, for which no final regulation requiring premarket approval has been promulgated, to market the device by complying with the FDA's 510(k) notification process. Similarly, the SMDA codified the FDA's definition of substantial equivalence. See *21 U.S.C. § 360c*(i)(1)(A). Because Congress in the SMDA codified FDA procedures in place at the time the device implanted into English was approved by the FDA pursuant to the 510(k) process, we make reference to its provisions in determining the extent to which the FDA has regulated the device." [Italics in original.]

Thus, while it is true that there are differences in approval procedures under the statute, the plain language of 21 U.S.C. § 360k(a) confirms that Congress chose not to recognize these differences when it came to write the preemption provision. The vice of the decision below, and that of the Eleventh Circuit in *Lohr*, is that both courts effectively rewrote Section 360k(a) as if Congress had not said *"any* requirement . . . which relates to the safety . . . of the device," but instead had said, "any stringent requirement imposed under the PMA process."

REASONS FOR GRANTING THE WRIT

Certiorari should be granted to resolve a mature circuit conflict on a question of importance, *viz.*: whether the 510(k) approval process of Class III medical devices does or does not trigger preemption of design-defect claims under 21 U.S.C. § 360k(a).

1. *Cippollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), confirmed that express preemption by an Act of Congress applies with equal force to state legislative acts and to product liability suits brought under state law principles. Once that question was settled, the post-*Cippollone* decisions of the lower courts rather quickly held that the great majority of product liability claims involving Class III medical devices are preempted by the plain language of 21 U.S.C. § 360k(a). As we have said, the circuits are in general agreement that failure to warn and manufacturing defect claims are preempted by reason of the FDA's labeling and good manufacturing practice regulations, respectively. *Ante*, pp. 4-5 and cases cited.[4]

2. Therefore, among the trilogy of typical product liability claims, only preemption of "design defect" claims remains uncertain, by reason of the circuit conflict to which we have drawn attention. This Court's resolution of this one remaining issue would complete the picture, thereby enabling lower courts to resolve all

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[4] Only the panel opinion in *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (CA 9, 1995) *(pet'n for r'hrg pending)*, rejects the view that Section 360k(a) has no application to product liability litigation involving medical devices.

issues of medical device preemption upon a completed slate of decisional authority.

3. The conflict is ripe for resolution because just about everything that could be said on the subject has been said in the four courts of appeals opinions to which we have referred – those of the Third and Fourth Circuits, on the one hand, and of the Fifth (below) and Eleventh, on the other. At bottom, each court agreed or disagreed with the district court's reasoning below, that the statute "does not require a threshold level of stringency that must be met before preemption attaches." App. 27. Additional decisions of other courts of appeals are unlikely to produce any new or different analysis; more likely, they will simply align themselves with one or the other of the competing current views.

4. The importance of the need for resolution of the question presented is also manifest. In the MDA, Congress recognized both the need for preemption as an incentive to medical device innovation, and the impracticality of banning pre-Act or substantially equivalent medical devices from commerce for howsoever long it might take the FDA to approve them under the PMA process. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976); S. Rep. No. 33, 94th Cong., 2d Sess. 2 (1976 U.S.C.C.A.N. 1070, 1071); *English v. Mentor Corp., supra*, 67 F.3d at 479 & n.1. Congress therefore chose to adopt a scheme for "gradual compliance" with the PMA process. *Id.* But at the same time, Congress did not adopt a scheme for "gradual preemption"; Section 360k(a) draws no such distinction, for words clearer than *"any requirement applicable under this chapter"* would be difficult to imagine.

5. When it came to codify the agency's 510(k) process for approval of medical devices substantially equivalent to those on sale before the 1976 adoption of the MDA, Congress observed that "over 80 percent of the devices that are the potentially most dangerous (Class III) enter the market" under the 510(k) process. H.R. Rep. 808, 101st Cong., 2d Sess. 14 (1990 U.S.C.C.A.N. 6305, 6307). The decision below, and that of the Eleventh Circuit in *Lohr, supra*, thus deny preemption to the great majority of current Class III devices, without even the slightest hint that Congress intended this result. These courts have thus converted "gradual compliance" with PMA procedures into "gradual preemption" under the Act. Surely this is a question on which – further debate being unlikely – this Court should now express the last word.

6. Finally, the Court may fairly ask whether, if it should grant the writ in *Medtronics*, No. 95-754, it should also do so here. Respectfully, it should, because the records made as to the 510(k) submissions of the two manufacturers, each involving a different device (and in petitioner Mentor's case, a submission augmented by its IDE program data) may assist the Court in gaining a better understanding of the breadth of the FDA's regulatory process.

CONCLUSION

The petition for a writ of certiorari to the United States Court of Appeals for the Fifth Circuit should be granted.

DATED: December 26, 1995

Respectfully submitted,

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APPENDIX A

Sam FELDT, Plaintiff-Appellant

v.

MENTOR CORPORATION, Defendant-Appellee

No. 94-20592

United States Court of Appeals
for the Fifth Circuit

August 21, 1995

Before WISDOM, GARWOOD and DAVIS, Circuit Judges.

GARWOOD, Circuit Judge:

In this products liability suit, plaintiff-appellant Sam Feldt (Feldt) appeals the district court's award of summary judgment, on the basis of preemption, for defendant-appellee Mentor Corporation (Mentor). We affirm in part, reverse in part, and remand.

Facts and Proceedings Below

On October 19, 1988, in an effort to cure erectile impotency, Feldt, then 68 years old, had implanted a pump-activated, Mentor GFS inflatable penile prosthesis (the prosthesis of the GFS), which had been approved by the Food and Drug Administration (the FDA) for marketing because of its substantial equivalence to prior devices. Feldt's prosthesis worked until June 1991, when, because of a flaw in the connection between the penile cylinders and the scrotal pump reservoir, it would no longer inflate and had to be removed and replaced. Feldt claims that, as a result of this defect, he suffered from

embarrassment, trauma, and decreased sexual desire. He also claims that the defect contributed to the end of his relationship with his fiancee.

Seeking recovery for these and other injuries, Feldt filed suit against Mentor, the product manufacturer, in Texas state court on June 17, 1993, alleging negligence, strict products liability, breach of express and implied warranties, and violations of the Texas Deceptive Trade Practices Act (DTPA). In its answer, Mentor raised eighteen affirmative defenses, among them the complete preemption of Feldt's state law claims. Asserting diversity and federal question jurisdiction, Mentor removed the suit to federal court, where on May 20, 1994, it filed a motion for summary judgment based only on the preemption defense. Feldt opposed the motion but dropped his negligence and strict liability claims with regard to the GFS's manufacture. On July 11, 1994, the district court awarded Mentor summary judgment, from which Feldt now appeals.

Discussion

The only issue in this appeal is whether 21 U.S.C. § 360k(a), part of the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug and Cosmetic Act, expressly preempts Feldt's remaining state law claims.[1] When the field alleged to be preempted by federal law

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[1] Although Feldt dropped his negligence and strict liability claims based on defective manufacture, he preserved his failure-to-warn and defective-design claims, which are also grounded on theories of negligence and strict liability.

has been traditionally occupied by the states, there is a presumption against preemption that can be rebutted only by a "clear and manifest" congressional purpose, be it express or implied. *Jones v. Rath Packing Co.*, 430 U.S. 519, 525, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977). When Congress explicitly displaces state law, however, as it has here, congressional intent is determined with reference only to the express language of the statute; preemption will not be implied. *Cipollone v. Liggett Group, Inc.*, ___ U.S. ___, ___, 112 S.Ct. 2608, 2618, 120 L.Ed.2d 407 (1992); *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1420 (5th Cir.) (rejecting the argument that the language of the MDA permits a finding of implied preemption), *cert. denied*, ___ U.S. ___, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993). The federal statute at issue, section 360k(a) of the MDA, provides as follows:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a).

The parties dispute whether Texas law establishes, with respect to the GFS, "any requirement different from, or in

addition to, any requirement applicable under this chapter to the device."[2] *Id.*

Since the enactment of the MDA in 1976, the FDA has had authority to regulate the entry of medical devices into the market. Pursuant to this authority, the FDA groups medical devices into three classes (Classes I-III) according to the amount of regulation necessary to ensure their safety and effectiveness. Although all classes of medical devices are subject to general controls, including labeling requirements and so-called good manufacturing practices (GMPs), Class II and Class III devices are subject to additional regulations. Moreover, because Class III devices are deemed to pose the greatest threat of illness or injury, they are subject to the most stringent regulation of the three classes. The GFS is a Class III device. 21 C.F.R. § 876.3350(b).

Before being marketed and sold, Class III devices must undergo the rigors of Pre-Market Approval (PMA), a lengthy, comprehensive process, at the end of which the FDA determines whether there is "reasonable assurance" that the device under consideration is safe and effective. *See* 21 U.S.C. § 360d(c)(1), (d); *see also Reeves v. AcroMed Corp.*, 44 F.3d 300, 303 (5th Cir.), *cert. denied*, ___ U.S. ___, 115 S.Ct. 2251, 132 L.Ed.2d 258 (1995). As this Court recently summarized,

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[2] We have held that state requirements subject to preemption by the MDA may be positive enactments or common law duties. *Stamps*, 984 F.2d at 1420; *see also Cipollone*, ___ U.S. at ___, 112 S.Ct. at 2620. Feldt thus draws no distinction between his statutory and common law claims.

> The FDA's [PMA] application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. . . . FDA regulations also require [PMA] applicants to submit "[c]opies of all proposed labeling for the device." 21 C.F.R. § 814.20(b)(10). The FDA approves a [PMA] application only after extensive review by the agency and an advisory committee composed of outside experts. *Id.*

Although as a general rule a Class III device must obtain PMA before it can be marketed to the public, 21 U.S.C. § 360e(c)(2), there are two exceptions. First, Class III devices found by the FDA to be "substantially equivalent" to devices on the market before May 28, 1976, the MDA's effective date, are entitled to bypass the PMA process. *Id.* § 360e(b)(1). Second, Class III devices that obtain an investigational device exemption (IDE) from the FDA, *id.* § 360j(g), may be clinically tested on humans without first obtaining PMA. *id.* § 360e(a). At any time, however, the FDA may issue a regulation requiring an exempted device to undergo the formal PMA process, *see id.* § 351(f)(2), but to date has not done so for inflatable penile prostheses.

It is undisputed that Mentor never obtained PMA for the GFS. The prosthesis was instead found by the FDA to be substantially equivalent to devices marketed before the MDA's effective date. A finding of substantial equivalence is based on a section 510(k) statement submitted as part of a pre-market notification application, a process significantly more abbreviated and less involved than

PMA.[3] *Reeves*, 44 F.3d at 303. Applicants for pre-market notification must submit device descriptions and other information sufficient for the FDA to determine whether the device in question is substantially equivalent to pre-MDA marketed devices. As with the application for PMA, applicants must also submit their proposed labeling, 21 C.F.R. § 807.87, for the FDA to determine compliance with general labeling regulations. See 21 C.F.R. § 801 *et seq.*; *Reeves*, 44 F.3d at 305. In this case, Mentor filed a 510k notification for the GFS on June 9, 1987, and included a variety of information relating to the design of the product as well as a summary of a nine-month clinical evaluation performed pursuant to a previously approved IDE. *See English v. Mentor Corp.*, 1994 WL-263353 at 4-5 (E.D.Pa. June 13, 1994) (unpublished) (describing the content of Mentor's 510k statement). The FDA approved the pre-market notification application on August 26, 1987, thereby allowing the GFS to enter the market subject only to general controls, at least until the FDA requires by regulation that the prosthesis undergo PMA.

Whether the pre-market notification procedures and general controls, like the PMA process, constitute "any requirement(s] applicable . . . to the device" so as to displace any additional or different state requirements (relating to the product's safety or effectiveness), 21 U.S.C. § 360k(a), is the central question in this case. The

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[3] Mentor was also granted an IDE, pursuant to which it conducted clinical trials of the prosthesis. Approval for the implant of Feldt's GFS, however, was not connected to this clinical program, but was instead based only on Mentor's pre-market notification and the subsequent FDA determination of substantial equivalence.

test for section 360k preemption in this Circuit tracks the statutory language:

> A state tort cause of action will be preempted if, in the context of the particular case, it (1) constitutes a requirement different from, or in addition to, any requirement the MDA makes applicable to the device at issue and (2) relates either to (a) the safety or effectiveness of the device or (b) any other matter included in a requirement made applicable to the device by the MDA. *Stamps*, 984 F.2d at 1421.

There is no question that the state law duties in question are requirements relating to safety and effectiveness. The only issue, then, is whether there is "any requirement the MDA makes applicable to the device at issue."

Below and on appeal, Feldt has argued that although state law imposes duties on manufacture of medical devices, these duties are not "in addition to" any federal requirements because no such requirements exist until the FDA requires PMA for penile prostheses. Rejecting this contention, the district court determined that the FDA's regulations relating to pre-market notification were requirements to which all Mentor state law duties were "in addition" and therefore preempted. On appeal, Feldt argues mainly that the regulations now applicable to the GFS are for identification and classification only and therefore should not, in light of the MDA's purpose consumer protection, be construed as federal requirements within the meaning of section 360k. Instead, Feldt contends, consumers should be allowed to pursue state law claims until the FDA promulgates requirements specifically applicable to the GFS.

This Court has considered the preemptive scope of the MDA in a trio of opinions, beginning with *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 246-47 (5th Cir. 1989). In *Moore*, we held that section 360k(a) preempted a claim that the manufacturer of a Class II device, a tampon, had failed to adequately warn plaintiff of the dangers of toxic shock syndrome. We reasoned that because FDA regulations specifically prescribe the form and content of toxic shock warnings on tampons, the recognition of a state law tort duty would in effect impose labeling requirements on the manufacturer beyond those required by the FDA. The plaintiff, however, also brought a strict liability claim premised on the manufacturer's allegedly defective construction and design of the tampon. Because "[t]here are no federal regulations on tampon design, composition, or construction," we held that plaintiff's defective design claims were preempted. *Id.* at 246.

In *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir.), *cert. denied*, ___ U.S. ___, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993), we held that section 360k(a) preempted a plaintiff's failure-to-warn claim against a manufacturer of a Class III device (anti-wrinkle cream) even though the FDA had not promulgated device-specific regulations prescribing the form and content of the product's labels and warnings. *Id.* at 1423-24. According to the Court, the "Class III regulatory structure, no less than that of Class II," imposed general requirements on the proposed labeling and warnings of the device that were "different from, or in addition to" those under Texas tort law. *Id.* at 1422. We also determined that the plaintiff's defective design and manufacturing claims were preempted because of the PMA process and the generally applicable GMPs. *Id.* at

1422 & n. 5. Together, these regulations left us "with little doubt as to whether the MDA tolerates different or additional state requirements, respecting design or manufacture. . . . " *Id.* at 1422 n. 5.

Finally, in *Reeves,* we held that section 360k(a) preempted the plaintiff's failure-to-warn claim against a manufacturer of a Class III device (metal bone implant) marketed without PMA. 44 F.3d at 305. Because the plaintiff's failure-to-warn claim would impose "labeling requirements beyond those required by the FDA," we concluded, the claim "runs afoul of § 360k(a) of the MDAs." *Id.* We rejected the plaintiff's basis for distinguishing *Stamps*: that the device at issue had not undergone the rigors of PMA but was instead marketed on the basis of substantial equivalence, an FDA finding that does not brand the product with official approval. We focused instead on the fact that pre-market notification, like PMA, imposes some requirements on labeling and warning, and held that it is the existence of any federal requirement that triggers the preemption analysis.[4] *Id.* Although the plaintiff in Reeves also brought claims relating to design and manufacturing defects, the defendant did not contend that these were preempted; the Court therefore did not address this issue.

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[4] In so holding, we agreed with an earlier decision of the First Circuit, *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994). Under facts virtually identical to these here, the court in *Mendes* concluded that section 360k(a) preempted the plaintiff's claims of implied warranty and failure to warn. The Court did not consider preemption of plaintiff's defective design claims because the plaintiff had abandoned them. *Id.* at 17-18.

Reeves forecloses Feldt's principal basis for distinguishing *Stamps*: that the pre-market notification process, unlike PMA, does not invoke the preemption provision of section 360k. Preemption does not depend on the route the product takes to the market, but on whether there are any specific federal requirements applicable to the device. *See Reeves*, 44 F.3d at 305 (holding that, "despite the differences between" PMA and pre-market notification, "our preemption analysis remains the same"). Furthermore, since *Moore*, it has become clear that these regulations need not be device-specific; they need only apply generally to the device at issue. In *Stamps*, this Court ruled that the test is whether there is "any requirement the MDA makes applicable to the device at issue." 984 F.2d at 1421.[5] Both *Reeves* and *Stamps*, moreover, identified as federal requirements certain general controls applicable to the Class III device, including the GMPs. *See Reeves*, 44 F.3d at 305; *Stamps*, 984 F.2d at 1422 n. 5

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[5] Citing the following provision, Feldt suggests, and amicus Public Citizen Inc. argues, that the FDA's own gloss on section 360k(a) requires device-specific regulation: "State or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements." 21 C.F.R. § 808.1(d). Although the requirements must be "specific" and applicable to a "particular" device, there is no language mandating that such requirements be specifically applicable to the device. In *Stamps*, this Court labelled the FDA's test "essentially the same" as the one set forth in that opinion. 984 F.2d at 1421 n. 2. Moreover, this Court in *Reeves* based preemption on labeling regulations generally applicable to all Class III devices. 44 F.3d at 305.

(describing the GMPs of section 360j(f) as "further requirements").

In his reply brief, filed after this Court's decision in Reeves, Feldt appears to concede, as he must, that his failure-to-warn claims are preempted by regulations, both general and specific, on labels and warnings applicable to the GFS. *See* 21 C.F.R. § 801.1 *et seq.*; *id.* § 895.25; *see also id.* § 801.109 (relating only to prescription devices). In *Reeves*, this Court relied on the same non-PMA provisions relating to labels and warnings that apply to the prosthesis in this case. *Reeves*, 44 F.3d at 305. We therefore hold that Feldt's claims are preempted to the extent they are grounded on allegations of inadequate warnings or labeling. *See also Mendes*, 18 F.3d at 18. The district court did not err in finding preempted Feldt's failure-to-warn claim.[6]

That there are some specific requirements applicable to the GFS, however, does not necessarily mean that all Feldt's claims are thereby preempted. As *Moore* and even *Reeves* make plain, there must be some nexus between the state and federal requirements to trigger section 360k preemption. *See also Cipollone*, ___ U.S. ___ at ___, 112 S.Ct. at 2621-23. In *Reeves*, for instance, the plaintiff's inadequate warning claims were preempted not because

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[6] Although Feldt does not discuss his claim of negligent marketing, the claim is essentially based on a failure to warn and is likewise preempted. *See Lujan v. Tampo Mfg. Co., Inc.*, 825 S.W.2d 505, 510 (Tex.App.___ El Paso 1992, no writ) (a claim of negligent marketing "involves a failure to warn, or warn adequately, of dangers or risks of harm or the failure to provide instructions for safe use of the particular product").

of the FDA's GMPs, but only because of its specific regulations on labels and warnings. Furthermore, in *Moore*, we determined that there was no preemption of the plaintiff's defective construction and design claims because there were "no federal regulations on [the device's] design, composition, or construction." 867 F.2d at 246. The district court thus erred in relying on the labeling regulations and GMPs as adequate grounds to automatically preempt all Feldt's claims. We therefore consider Feldt's remaining claims, those based on implied warranty, defective design, and the DTPA.

With regard to his implied warranty claim, Feldt alleges that Mentor impliedly represented that the GFS was merchantable and fit for its intended purpose. *See* Tex.Bus. & Com. Code §§ 2.314, 2.315. In Texas, these warranties arise by operation of law for any sale of goods in Texas.[7] *Dennis v. T.H. Allison*, 698 S.W.2d 94, 94-95 (Tex.

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[7] Although Feldt also alleged a breach of an express warranty based on advertising and product literature, he does not specifically discuss any express warranty claim, as such, in his brief. We therefore deem abandoned any contentions on appeal regarding the preemption of this particular claim, *L & A Contracting v. Southern Concrete Services*, 17 F.3d 106 (5th Cir. 1994) (issues not adequately briefed deemed abandoned on appeal), and as a result do not decide whether express warranties are preempted by section 360k, given that they arise not by operation of law but by agreement. *See American Airlines, Inc. v. Wolens*, ___ U.S. ___, ___, 115 S.Ct. 817, 824, 130 L.Ed.2d 715 (1995) (distinguishing state-imposed from contractually imposed obligations); *Cipollone*, ___ U.S. at ___, 112 S.Ct. at 2622 (same). *See also Michael*, 46 F.3d at 1325-28 (holding that section 360k(a) does not preempt claims relating to the breach of express warranties).

1985). Liability under these provisions depends on a finding that the goods are defective, meaning that they are "unfit for the ordinary purposes for which they are used because of a lack of something necessary for adequacy." *Plas-Tex, Inc. v. U.S. Steel Corp.*, 772 S.W.2d 442, 444 (Tex. 1989). The defect, moreover, may be one of "design, material, or manufacture." *Clark v. DeLaval Separator Corp.*, 639 F.2d 1320, 1326 (5th Cir. 1981). At oral argument, Feldt maintained that he is not pursuing a warranty claim based on defective manufacture, but only on defective design.[8]

With respect to the design of the GFS, Mentor has not cited, nor can we find, any specific, applicable FDA regulations. Pre-market notification, as mentioned earlier, does not necessarily entail an assessment, and certainly not an affirmation, of the adequacy or quality of the product's design. Although the generally applicable GMPs regulate the manufacture of the GFS, and although PMA devices are deemed "safe and effective," Mentor has identified no comparable regulations relating specifically to the design quality of non-PMA Class III devices generally or of the GFS in particular. Because the design of the device is not specifically addressed by regulation, we hold that Feldt may proceed with so much of his implied warranty claim as relates to the allegedly defective design of the prosthesis.[9]

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[8] The First Circuit has explicitly held that the GMPs preempt implied warranty claims based on defective manufacture. *Mendes*, 18 F.3d at 19.

[9] We acknowledge that our holding in this respect is perhaps in tension with a recent decision from the Third Circuit,

The same conclusion holds for Feldt's tort-based claims of defective design.[10] In *Moore*, this Court specifically held that, because there were no regulations concerning the tampon's "design, composition, or construction," the plaintiff could proceed with a defective design claim. Although *Moore* concerned a Class II device that apparently did not have to comply with the procedures for pre-market notification, there is no indication here of any general Class III regulations specifically concerning the safety or adequacy of the GFS's design. We recognize that at least two district courts, on virtually identical facts, have held that the plaintiffs' defective-design claims were preempted, in part because of the pre-market notification process. *See Bokis v. American Medical Systems, Inc.*, 875 F.Supp. 748, 755 (W.D.Ok. 1995); *English*

Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir.1995). In *Michael*, the court relied in part on the GMPs to conclude that the plaintiff's design-related implied warranty claim was preempted. *Id.* at 1325. Michael is distinguishable, however, because the decision was clearly grounded on the fact that the device had undergone PMA; indeed, it is not certain that the Third Circuit would have found the GMPs to be an independently adequate basis for the preemption of claims relating to design. The same can be said of our decision in *Stamps*, where we mentioned in passing the GMPs in reference to claims relating to both design and manufacturing. *See Stamps*, 984 F.2d at 1422 n. 4. It is clear that *Stamps*, especially when viewed in light of *Moore*, premised the preemption of the plaintiff's defective-design claims on the fact that the device had undergone PMA.

[10] In contrast, the term "defect" under Texas tort law "means a condition of the product that renders it unreasonably dangerous." *Plas-Tex*, 772 S.W.2d at 444. Whether a product is unreasonably dangerous or inadequately fit for its intended purpose may be, in either case, a question of the product design.

v. Mentor Corp., 1994 WL 263353 (E.D.Pa. June 13, 1994) (unpublished). Neither court, however, explained how pre-market notification imposes requirements regarding the device's design. Indeed, the most the manufacturer is required to do in its 510k statement is describe the device in a way that establishes that the device "has the same technological characteristics" or, if not, that it is "as safe and effective" as a predicate device, 21 U.S.C. § 360c(i)(1)(A);[11] there are, in short, no requirements or

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[11] At oral argument, Mentor contended that a finding of substantial equivalence necessarily means that an approved device is no less safe than the predicate device. Consequently, the question arises whether Feldt's design claims should be preempted at least to the extent they rely on allegations that the device is defective because of differences between it and the predicate device. Although 21 U.S.C. § 360c(i) is the law today and has been since 1990, it is unclear what necessarily went into a finding of substantial equivalence at the time the GFS was approved for marketing in 1987. At that time, what determined substantial equivalence was not controlled by statute, and Mentor has not cited, nor can we find, any regulations or case law to support its position that the GFS has necessarily been found to be as safe and effective as predicate devices. With regard to design, the FDA regulations applicable in 1987 appear to have required only "[a] statement indicating the device is similar to and/or different from other products of comparable type, . . . accompanied by data to support the statement." 21 C.F.R. § 807.87(f). Safety information was required only if the new device "has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device." *Id.* § 807.87(g). There is nothing in the record that clearly indicates whether the GFS is technologically different from the predicate devices to which it was found to be substantially equivalent. In any event, it does not appear that Feldt has grounded his defective design claims on any differences in design between the GFS and its predicates.

prohibitions specifically regarding the design of non-PMA Class III devices. Indeed, in the letter approving Mentor's 501k statement, the FDA stated that its finding of substantial equivalence did not necessarily indicate approval of the GFS's design. At the very least, then, the nexus between the state and federal requirements is much weaker with respect to design defects than it is with respect to manufacturing and labeling, and we find this nexus inadequate to justify the displacement of state law regarding defective design.[12]

Finally, Feldt has alleged violations of the DTPA. With regard to this claim, Feldt's complaint focuses on representations regarding the GFS's design quality. To the extent Feldt's DTPA claims relate to general marketing or advertising of the device, they are preempted by the FDA's explicit regulations on labels and warnings. To the extent the DTPA claims are based on the breach of an implied warranty, however, the preemptive effect is the same as for Feldt's implied warranty claim under the Texas Business and Commerce Code, discussed above.

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[12] According to one district court, a jury finding that the GFS is unreasonably dangerous "would be contrary to the determinations necessarily made by the FDA" under its procedures for pre-market notification. *Bokis*, 875 F.Supp. at 755. The FDA, however, may approve an unreasonably dangerous device so long as the device has the same technological characteristics or, if the device has different technological characteristics, is as safe and effective as the predicate device. 21 U.S.C. § 360c(i). To say that a new device is as safe as its predicate thus indicates nothing, absolutely, about how safe either product is; a new device may be as safe as a predicate device that itself is unreasonably dangerous.

Conclusion

For the foregoing reasons, we reverse the district court's judgment insofar as it holds that Feldt's state law claims of design defect are preempted; we affirm the remainder of the judgment and remand the cause for further proceedings consistent with this opinion.

AFFIRMED in part, REVERSED in part, and REMANDED.

APPENDIX B

U.S. COURT OF APPEALS
FILED
Sep 26 1995
Charles R. Fulbruge III
Clerk

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 94-20592

SAM FELDT,

Plaintiff-Appellant,

versus

MENTOR CORPORATION,

Defendant-Appellee.

Appeal from the United States District Court for the Southern District of Texas

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ON PETITION FOR REHEARING

(September 26, 1995)

Before WISDOM, GARWOOD and DAVIS, Circuit Judges.

PER CURIAM:

IT IS ORDERED that the petition for rehearing filed in the above case is DENIED.

ENTERED FOR THE COURT:

/s/ Will Garwood
WILL GARWOOD
UNITED STATES CIRCUIT JUDGE

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

SAM FELDT, Plaintiff,	§	CIVIL ACTION NO. H-93-2205
vs.	§	
MENTOR CORPORATION, Defendant.	§	

Memorandum and Order

Pending before this court is a motion for summary judgment filed by defendant Mentor Corporation ("Mentor"). (Docket Entry No. 44). After carefully considering the facts, parties' submissions, and applicable authority this court GRANTS the motion.

1. Factual and Procedural Background

Plaintiff Same Feldt ("Feldt") had a Mentor GFS inflatable penile prosthesis ("GFS") implanted on October 18, 1988. This device is used to treat erectile impotence. The GFS failed in June 1991 and was removed on August 22, 1991. The operative report stated that "the tubing leading to the right cylinder had become disconnected at the connector site on the pump side." (Docket Entry No. 45, Ex. C).

Feldt filed suit against Mentor, alleging negligence, product liability, breach of the Texas Deceptive Trade Practices Act ("DTPA"). (Docket Entry No. 15). In its

answer, Mentor raised eighteen affirmative defenses, including preemption. Feldt then dropped his claims of strict liability for a manufacturing defect and for negligence in manufacture. Mentor has moved for summary judgment on the ground that federal law preempts all of plaintiff's claims.

2. Summary Judgment Standard

Summary judgment is appropriate if no genuine issue of material fact exists and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56. A fact is "material" if its resolution in favor of one party might affect the outcome of the suit under governing law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S.Ct. 2505, 2510 (1986). "Factual disputes that are irrelevant or unnecessary will not be counted." *Anderson*, 477 U.S. at 248, 106 S.Ct. at 2510. An issue is "genuine" if the evidence is sufficient for a reasonable jury to return a verdict for the nonmoving party. *Anderson*, 477 U.S. at 248, 106 S.Ct. at 2510. If the evidence rebutting the motion for summary judgment is only colorable or not significantly probative, summary judgment should be granted. *Anderson*, 477 U.S. at 249-50, 106 S.Ct. at 2511; see *Lewis v. Glendel Drilling Co.*, 898 F.2d 1083, 1088 (5th Cir. 1990), *cert. denied*, 112 S.Ct. 171 (1991). In deciding a summary judgment motion, "[t]he evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor." *Anderson*, 477 U.S. at 255, 106 S.Ct. at 2513. If reasonable minds can differ regarding a genuine issue of material fact, summary judgment should not be granted. *Anderson*, 477 U.S. at 250-51, 106 S.Ct. at 2511.

3. Background

Congress enacted the Food, Drug, and Cosmetic Act ("FDCA") in 1938, delegating to the Food and Drug Administration ("FDA") authority to promulgate regulations to enforce the Act. *See* 21 U.S.C. § 371(a). In 1976, Congress enacted the Medical Device Amendments ("MDA"), granting the FDA comprehensive and exclusive regulatory authority over medical devices. *Id.* § 360c-360l.

Under the MDA, all medical devices intended for human use are classified into one of three categories. Class III devices, such as Mentor's prosthesis, "present a potential unreasonable risk of illness or injury." They are subject to the most stringent regulation through a premarket approval ("PMA") process before they may be distributed to the public. *Id.* § 360c(a)(1)(C).

The PMA process requires the manufacturer of a Class III device to submit a detailed application to the FDA that includes information about investigations relating to safety and effectiveness, product specifications, intended use, manufacturing methods and proposed labeling. *Id.* § 360e(c)(1). The FDA generally refers each application to a panel of qualified experts that prepares a report and recommendation with respect to the approval of the application. *Id.* § 360e(c)(2). Within six months, the FDA must either accept or reject the application for PMA. *Id.* § 360e(d).

The rule that a Class III device must obtain PMA before it can be marketed to the pubic has two exceptions. Class III devices that are found by the FDA to be "substantially equivalent" to devices on the market before the

MDA became effective in 1976 are entitled to bypass the PMA process unless or until the FDA issues a regulation requiring that the device undergo the PMA review process. *Id.* § 360e(b)(1). Class III devices that obtain an Investigational Device Exemption ("IDE") from the FDA, *id.* § 360j(g), may be clinically tested on human subjects without first obtaining PMA. *Id.* § 360e(a).

A manufacturer that intends to market a medical device pursuant to the substantial equivalence process must submit a premarket notification to the FDA at least 90 days before introducing the device into interstate commerce for commercial distribution. 21 C.F.R. § 807.81. The 510k notification must contain "an adequate summary of any information respecting [the] safety and effectiveness [of the device] or state that such information will be made available upon request by any person." 21 U.S.C. § 360c(i)(3)(A). The summary must contain "detailed information regarding the data concerning adverse health effects and shall be made available to the public by the [FDA] within 30 days of the issuance of a determination that such device is substantially equivalent to another device." 21 U.S.C. § 360c(i)(3)(B).

The FDA has issued regulations governing both the format of a 510k notification, 21 C.F.R. § 807.90, and the information a 510k notification must contain. 21 C.F.R. § 807.87. A 510k notification must include the following information: the device's name; the manufacturer's registration number; the classification of the device, and, if known, its appropriate panel; any action taken by the manufacturer to comply with the MDA's requirements for performance standards; proposed labels, labeling, and advertisements sufficient to describe the device, its

intended use, and the directions for its use; where applicable, photographs or engineering drawings of the device; a statement indicating that the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement that may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device; and any additional information regarding the device requested by the FDA that is necessary for the FDA to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. 21 C.F.R. § 807.87.

It is undisputed that Mentor filed a 510k notification for the GFS device on June 9, 1987. (Docket entry No. 44, Ex. C3). This 510k notification included the information referenced above as well as a summary of a nine-month clinical evaluation conducted pursuant to the FDA-approved IDE for the GFS. (Docket entry No. 44, Ex. C2, p. 4). The 510k notification incorporated data that was submitted as part of the device's IDE application, including: "Clinical Investigation Protocol, Clinical and Biological Testing, Physical and Mechanical Testing, Manufacturing and Quality Procedures, Sterilization Procedures, and Biological Test Reports." (Docket entry No. 44, Ex. C2, p. 2).

On August 26, 1987, after reviewing Mentor's 510k notification, the FDA determined that the prothesis was substantially equivalent to devices marketed before the enactment of the MDA. The FDA therefore approved the marketing of the prothesis subject to the general controls

provisions of the FDCA, including the MDA's good manufacturing practice requirements. (Docket entry No. 44, Ex. C3). The FDA noted that the prothesis, as a Class III device, would be required to undergo premarket approval at some time in the future. *Id.* The implantation of Feldt's prothesis occurred after the device had been cleared for marketing through the FDA's substantial equivalence determination.

4. Preemption

The MDA contains the following express preemption provision:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a). The FDA has interpreted the preemption law as follows:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the Act, thereby making any existing divergent State or local requirements applicable to the device different

> from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d). An agency's interpretation of its own statute generally controls, unless the interpretation is contrary to congressional intent. *Chevron U.S.A. v. Natural Resources Defense Council, Inc.*, 104 S.Ct. 2778, 2781-82 (1984).

The Fifth Circuit has held that under the preemption language of the MDA, "[s]tate tort causes of action to the extent they relate to safety, effectiveness, or other MDA requirements – constitute requirements 'different from, or in addition to' the Class III process; they are therefore, preempted." *Stamps v. Collagen Corp.*, 984 F.2d 1416, 1424 (5th Cir.), *cert. denied*, 114 S.Ct. 86 (1993). This holding is consistent with cases decided in other circuits, holding that state law tort claims against the manufacturer of a Class III medical device released to the market under a substantial equivalence finding are preempted. *Mendes v. Medtronic, Inc.*, 18 F.3d 13 (1st Cir. 1994); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 114 S.Ct. 84 (1993).

In *Stamps*, the Fifth Circuit held that the plaintiff's state law causes of action were preempted due to the PMA process for the Class III product at issue. *Stamps*, 984 F.2d at 1424 n.8. In the present case, the FDA allowed Mentor to market the GFS through the 510k notification process. The issue before this court is whether the section 510k notification process, like the PMA process, preempts the state law causes of action Feldt asserts.

Feldt relies upon *Larsen v. Pacesetter Sys.*, 837 P.2d 1273 (Haw. 1992), to argue that the federal regulations

applicable to the GFS are not preemptive. In *Larsen*, the Hawaii Supreme Court held that the MDA did not preempt state law claims because there were "no specific statutes or regulations applicable to the particular device in question in this case." *Id.* at 1282. In reaching this conclusion, the *Larsen* court relied on the premise that "the statutes and regulations governing premarket approval set forth general procedural requirements and, therefore, do not trigger a preemption analysis under § 808-1(b)." *Id.* This holding is directly contrary to the Fifth Circuit's ruling in *Stamps*. 984 F.2d at 1423.

Feldt also argues that, under *Stamps*, only the PMA process preempts the application of state law claims. However, as the *Stamps* court noted, the MDA's preemption applies to "any requirement imposed upon the device" and "a specific requirement applicable to a particular device." 984 F.2d at 1424. The MDA does not require a threshold level of stringency that must be met before preemption attaches.

The 510k notification process clearly imposes "requirements upon a device." These requirements for marketing the GFS Class III medical device under the substantial equivalence process constitute specific regulations made applicable to the GFS implants and relate to the safety or effectiveness of the device. These requirements preempt Feldt's state law tort claims.

The result is consistent with that reached by a number of other courts faced with the identical issues. *See, e.g., English v. Mentor Corp.*, 1994 WL 263353 (E.D. Pa. June 13, 1994); *Duvall v. Bristol-Myers*, CA No. 93-1072(D. Md. Mar. 30, 1994); *Rutland v. Mentor Corp.*, CA No.

20,235 (Harrison County, Miss. Cir. Ct. Feb. 23, 1994); *Gondeau v. Mentor Corp.*, CA No. 92-2149 (N.D. Ohio Dec. 14, 1993); *see also Bollier v. Medtronic, Inc.*, CA No. 92-2439 (S.D. Tex. Oct. 27, 1993).

This court also finds that Feldt's claims for failure to warn, breach of warranty, and DTPA violations are preempted by the MDA's labelling and good manufacturing practice requirements. As the Fifth Circuit stated in *Stamps*, " . . . [Section] 360j(f)'s '[g]ood manufacturing practice requirements' impose further requirements upon the manufacture of Class III devices, leaving us with little doubt as to whether the MDA tolerates different or additional state requirements, respecting *design or manufacture*, in the form of common law products liability duties." *Stamps*, 984 F.2d at 1422 n.5 (emphasis added).

This result is also consistent with that reached by other courts. In *Mendes v. Medtronic*, 18 F.3d 13 (1st Cir. 1994), suit was brought against a pacemaker manufacturer alleging numerous state law causes of action. The pacemaker had been placed on the market under the 510k notification process. *Mendes*, 18 F.3d at 17. The only requirements under the MDA applicable to the pacemaker were the regulations on labelling and "good manufacturing practices." *Id.* The First Circuit held that these requirements preempted the plaintiff's claims for negligence and breach of warranty. *Id.* at 18-20.

5. Conclusion

This court concludes that Feldt's state law claims are preempted under both the 510k notification process and

the requirements imposed for labelling and "good manufacturing practices." This court therefore GRANTS summary judgment in favor of Mentor.

The parties are ORDERED to inform the court within 10 days after this order is entered of the issues that remain in this case.

SIGNED on *July 11* , 1994, at Houston, Texas.

/s/ Lee H. Rosenthal
Lee H. Rosenthal
United States District Judge

APPENDIX D

21 U.S.C. § 360(k) (1994)

§ 360. Registration of producers of drugs or devices

. . . .

(k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall by regulation prescribe) –

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

21 U.S.C. § 360c(f)(3)

§ 360c. Classification of devices intended for human use

. . . .

(f) Initial Classification of certain devices

. . . .

(3) If a manufacturer reports to the Secretary under section 510(k) [21 USC § 360(i)] that a device is substantially equivalent to another device

> (A) which the Secretary has classified as a class III device under subsection (b),
>
> (B) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and
>
> (C) for which no final regulation requiring premarket approval has been promulgated under section 515(b) [21 USC § 360e(b)],

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 510(k) [21 USC § 360(k)] a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the section 510(k) [21 USC § 360(k)] report is being made and which has not been submitted to the Secretary under section 519 [21 USC § 360i]. The Secretary may require the manufacturer to submit the

adverse safety and effectiveness data described in the report.

21 U.S.C. § 360c(i)

§ 360c. Classification of devices intended for human use

. . . .

(i) Substantial equivalence.

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l) [21 USC § 360j(l)], the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device –

(i) has the same technological characteristics as the predicate device, or

(ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant

change in the materials, design, energy source, or other features of the device from those of the predicate device.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 510(k) [21 USC § 360(k)] respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

21 C.F.R. § 807.81(a)(3) (1995)

§ 807.81 When a premarket notification submission is required.

(a) Except as provided in paragraph (b) of this section, each person who is required to register his establishment pursuant to § 807.20 must submit a premarket notification submission to the Food and Drug Administration at least 90 days before he proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device

intended for human use which meets any of the following criteria:

. . . .

(3) The device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use. The following constitute significant changes or modifications that require a premarket notification:

(i) A change or modification in the device that could significantly affect the safety or effectiveness of the device, i.e., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process.

(ii) A major change or modification in the intended use of the device.

. . . .

21 C.F.R. § 807.87 (1995)

§ 807.87 Information required in a premarket notification submission

Each premarket notification submission shall contain the following information:

(a) The device name, including both the trade or proprietary name and the common or usual name or classification name of the device.

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submissions.

(c) The class in which the device has been put under section 513 of the act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of that determination and the basics for the person's determination that the device is not so classified.

(d) Action taken by the person required to register to comply with the requirements of the act under section 514 for performance standards.

(e) Proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use. Where applicable, photographs or engineering drawings should be supplied.

(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

(g) Where a person required to register intends to introduce into commercial distribution a device that has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device, or the device is to be marketed for a new or different indication for use, the premarket notification

submission must include appropriate supporting data to show that the manufacturer has considered what consequences and effects the change or modification or new use might have on the safety and effectiveness of the device.

(h) A 510(k) summary as described in § 807.92 or a 510(k) statement as described in § 807.93.

(i) For submissions claiming substantial equivalence to a device which has been classified into class III under section 513(b) of the act:

(1) Which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990; and

(2) For which no final regulation requiring premarket approval has been issued under section 515(b) of the act, a summary of the types of safety and effectiveness problems associated with the type of devices being compared and a citation to the information upon which the summary is based (class III summary). The 510(k) submitter shall also certify that a reasonable search of all information known or otherwise available about the class III device and other similar legally marketed devices has been conducted (class III certification), as described in § 807.94. This information does not refer to information that already has been submitted to the Food and Drug Administration (FDA) under section 519 of the act. FDA may require the submission of the adverse safety and effectiveness data described in the class III summary or citation.

(j) A statement that the submitter believes, to the best of his or her knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(k) Any additional information regarding the device requested by the Commissioner that is necessary for the Commissioner to make a finding as to whether or not the device is substantially equivalent to a device in commercial distribution. A request for additional information will advise the owner or operator that there is insufficient information contained in the original premarket notification submission for the Commissioner to make this determination and that the owner or operator may either submit the requested data or a new premarket notification containing the requested information at least 90 days before the owner or operator intends to market the device, or submit a premarket approval application in accordance with section 515 of the act. If the additional information is not submitted within 30 days following the date of the request, the Commissioner will consider the premarket notification to be withdrawn.

21 C.F.R. § 807.92 (1995)

§ 807.92 Content and format of a 510(k) summary

(a) A 510(k) summary shall be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence. FDA will accept summaries as well as amendments thereto until such time as FDA issues a determination of substantial equivalence. All 510(k) summaries shall contain the following information:

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

(2) The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has found to be substantially equivalent through the 510(k) premarket notification process;

(4) A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties;

(5) A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is

intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and

(6) If the device has the same technological characteristics (i.e, design material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.

(b) 510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:

(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence;

(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a

discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence; and

(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.

(c) The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a "510(k) summary."